

REMARKS

Claims 68, 69, 71, 72, 75-87, and 89-91 were pending. With the present Response, Applicants amend Claims 68, 85, and 89-91 and add new Claims 92-97. Therefore, Claims 68, 69, 71, 72, 75-87, and 89-97 remain pending for consideration. The Applicants respectfully request reconsideration in view of the enclosed amendments and remarks.

Claim Rejections Under 35 U.S.C. § 103

The Office Action rejects the following claims under 35 U.S.C. § 103(a): Claims 68, 69, 77, 81, and 84 as unpatentable over U.S. Patent No. 1,445,010 to Feinberg (hereinafter “Feinberg”) in view of U.S. Patent No. 5,005,571 to Dietz (hereinafter “Dietz”); Claims 71 and 91 as unpatentable over Feinberg in view of Dietz and further in view of European Publication No. EP0845277A2 to Daniell, et al. (hereinafter “Daniell”); Claim 72 as unpatentable over Feinberg in view of Dietz and further in view of U.S. Publication No. 2003/0196662 to Ging et al. (hereinafter “Ging”); Claims 75, 76, 78, and 90 as unpatentable over Feinberg in view of Dietz and further in view of U.S. Patent No. 6,012,455 to Goldstein (hereinafter “Goldstein”); Claims 79, 80, 82, and 83 as unpatentable over Feinberg in view of Dietz and further in view of European Publication No. EP 1075848 A2 to Robertson et al. (hereinafter “Robertson”); Claims 85-87 as unpatentable over Feinberg in view of Goldstein; and Claim 89 as unpatentable over Feinberg in view of Robertson and further in view of Daniell.

Although the Applicants respectfully traverse the rejections and do not acquiesce or necessarily agree with the Office Action’s characterizations of the applied art, Applicants have amended certain claims in order to expedite prosecution. Applicants provide the enclosed amendments without prejudice or disclaimer and Applicants reserve the right to pursue previous versions of the claims in one or more future patent applications.

Claims 68, 69, 77, 81 and 84

Claims 68, 69, 77, 81, and 84 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 1,445,010 to Feinberg in view of U.S. Patent No. 5,005,571 to Dietz. The Applicants respectfully traverse the rejection as the applied art, even if properly combined, fails to teach, suggest, or otherwise render obvious all of the claim language.

For example, Claim 68 recites, among other things (emphasis added):

68. A patient interface . . . comprising:
an elbow connector . . . ;
an outer flap adapted to conform to the user's mouth and in fluid
connection with said elbow connector *such that said outer flap applies a
compressive force around the user's mouth when worn* . . . ; and
nasal cannula

The Feinberg-Dietz combination fails to teach or suggest or otherwise render obvious at least a patient interface comprising an outer flap adapted to conform to the user's mouth such that said outer flap applies a compressive force around the user's mouth when worn.

In contrast, Feinberg merely describes a breathing apparatus for swimmers that includes a tubular passage 11 connected to a member 10 that communicates with a mouthpiece 12. The breathing apparatus permits "the user to submerge the head while swimming and to breathe freely while his head is thus positioned, without fear of being choked by water taken into the lungs through either the mouth or nostrils." *See* Feinberg, col. 1, lines 18-23.

Feinberg further explains:

The mouthpiece 12 is composed of rubber and is provided with the elongated flange 15 which is inserted into the mouth between the gums and lips of the mouth. A pair of projections 16-16 project inwardly from this flanged portion and are provided so that these portions may be inserted and held between the teeth. This flange 15 is spaced from the body of the member 10 so as to provide a space for the lips between it and the elongated flange 15.

Feinberg, col. 2, lines 68-78, *see also* Figures 1 and 3, reproduced below.

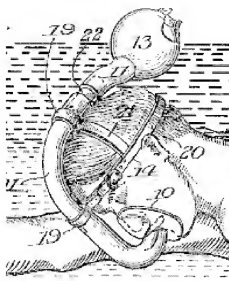


FIG. 1

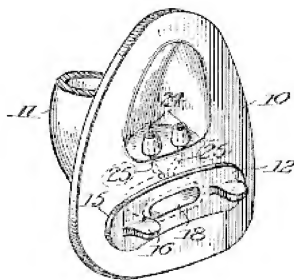


FIG. 3

Unlike the language of Claim 1, Feinberg fails to describe at least a patient interface comprising an outer flap adapted to conform to the user's mouth such that said outer flap applies a compressive force around the user's mouth when worn. In fact, Feinberg explains, "[F]lange 15 is spaced from the body of the member 10 so as to provide a space for the lips between it and the elongated flange 15." Because of the spacing between the body of member 10 and the flange 15, Feinberg's outer flap therefore need not even contact the wearer's face when worn, let alone conform to the user's mouth such that it applies a compressive force around the user's mouth.

Dietz fails to cure Feinberg's deficiencies, as Dietz merely describes a mask mounted on a patient's face ("the mask is mounted on the face of a patient independently of a nasal cannula and over the cannula without impeding its function"). See Dietz, Abstract and Figures 1 and 2, below.

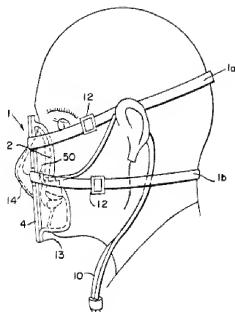


FIG. 1

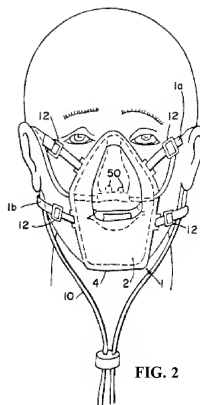


FIG. 2

Nowhere does Dietz teach or suggest a patient interface comprising an outer flap *adapted to conform to the user's mouth* such that said outer flap applies a compressive force *around the user's mouth* when worn. Therefore, for at least these reasons, the Feinberg-Dietz combination fails to render obvious the language of Claim 68. Claims 69, 77, 81 and 84 depend from Claim 68 and therefore distinguish over the applied art for at least the same reasons. In addition, Claims 69, 77, 81 and 84 distinguish over the applied art due to the unique combinations of features recited in those claims.

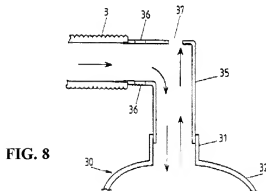
Claims 71 and 91

Claims 71 and 91 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Feinberg in view of Dietz and further in view of Daniell. Applicants respectfully traverse this rejection at least because even if properly combined, which it isn't, the applied art fails to teach, suggest, or

otherwise render obvious all of the claim language. Indeed, the Office Action improperly combines the applied art in a manner that impermissibly renders it unsuitable for its intended use.

For example, Claim 71 depends from Claim 68 and therefore distinguishes over the applied art for at least the same reasons discussed above with respect to Claim 68. In addition, Claim 71 distinguishes over the applied art due to the unique combination of features recited in that claim and because the Office Action improperly combines the applied art in an impermissible manner.

Daniell describes an apparatus and method of treating Obstructive Sleep Apnea wherein a positive airway pressure device provides a gases supply which is passed through a humidifier 8. *See Abstract.* Daniell explains (emphasis added), “swivel fitting 35 includes *an outlet 37* through which the patient's exhalatory gases may pass (if exhalation is through the mouth) and also enables a constant pressure to be maintained at the entrance to mouthpiece 30.” Daniell, col. 8, lines 32-26, *see also* Figure 8, reproduced below.



The Office Action improperly combines Daniell's swivel fitting 35 having an outlet 37 with Feinberg's breathing apparatus for swimmers to obtain, “a gas delivery apparatus that would allow a patient to exhale either through the nasal passageway and/or the mouth based upon the patient's individual breathing habits or desires.” Office Action, page 5. However, the Office Action fails to establish a motivation to combine these references as Feinberg alone, without the features taken from Daniell would by itself provide “a gas delivery apparatus that would allow a patient to exhale either through the nasal passageway and/or the mouth based upon the patient's individual breathing habits or desires.” Indeed, Feinberg's device includes both a mouthpiece 12

and “tubular extensions 24-24 . . . which are designed to be inserted into the nostrils.” Feinberg, column 3, lines 17-20.

In addition, not only is there no motivation to combine because the proposed modification is unnecessary, but it is also improper because it would render Feinberg unsuitable for its intended use as a “breathing apparatus for swimmers.” Feinberg, title.

The M.P.E.P. clearly explains that there is no suggestion or motivation to combine references where the proposed modification renders the art unsatisfactory for its intended purpose. M.P.E.P. 2143.01 section V (“[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)”).

A breathing apparatus for swimmers would necessarily be rendered unsatisfactory for its intended purpose (i.e., to provide air to a swimmer through a breathing tube) if an outlet, such as Daniell’s outlet 37, is incorporated into a breathing apparatus for swimmers “to allow diffusion of the user’s exhaled gases.” Indeed, such an outlet would necessarily allow water to enter the air passage through which a swimmer breathes underwater, thereby preventing the device to function as intended. Accordingly, the Office Action improperly combines the applied art in an impermissible manner. Therefore, for at least this reason, the Office Action fails to establish a prima facie case of obviousness of Claim 71.

Regarding Claim 91, the Office Action states, “the combined references lack the elbow connector having an outlet vent to allow diffusion of the user’s exhaled gas.” However, Applicants respectfully submit that the cited language is not, and prior to amendment was not, present in Claim 91. Claim 91 describes, among other things (emphasis added):

91. A system for delivery of gases to a user, said system comprising:
 - a gases source;
 - a breathing circuit . . . ; and
 - a patient interface . . . comprising:
 - an elbow connector capable of receiving gases from the source,
 - an outer flap that fits around and encloses said user’s mouth such that said outer flap applies a compressive force around the user’s mouth when worn . . . , and*
 - nasal cannula sealing in each of the nares of said user . . .

For reasons similar to those discussed above with respect to Claim 68, the applied art fails to teach, suggest, or otherwise render obvious, at least a system for delivery of gases to a user comprising a patient interface, the patient interface comprising an outer flap that fits around and encloses a user's mouth such that the outer flap applied a compressive force around the user's mouth when worn.

Therefore, for at least these reasons, Claim 91 distinguishes over the applied art.

Claim 72

Claim 72 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Feinberg in view of Dietz and further in view of Ging. Claim 72 depends indirectly from Claim 68 and therefore distinguishes over the applied art for at least the same reasons discussed above with respect to Claim 68. In addition, Claim 72 distinguishes over the applied art due to the unique combination of features recited in that claim. Furthermore, Claim 72 distinguishes over the applied art because the Office Action improperly combines the applied art in a manner that impermissibly renders it unsuitable for its intended use. M.P.E.P. 2143.01 section V. For reasons similar to those discussed above with respect to Claim 71, combining Feinberg's breathing apparatus for swimmers with Ging's "plurality of apertures (390) in the apex of an L-shape connector of [an] elbow connector[,] the apertures adapted to vent gases exhaled from the user" (see Office Action, page 6), renders Feinberg unsuitable for its intended use.

Claims 75, 76, 78 and 90

Claims 75, 76, 78, and 90 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Feinberg in view of Dietz and further in view of Goldstein. Applicants respectfully traverse the rejection, as the applied art fails to teach, suggest, or otherwise render obvious all of the claim language.

Indeed, Claims 75, 76, and 78 depend from Claim 68, and therefore distinguish over the applied art for at least the same reasons discussed above with respect to Claim 68. In addition, Claims 75, 76, and 78 distinguish over the applied art due to the unique combinations of features recited in those claims.

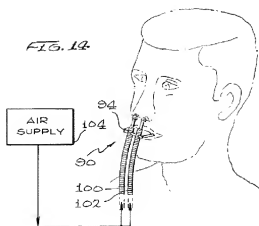
Claim 90 also distinguishes over the applied art due its unique combinations, as well. For example, Claim 90 describes, among other things (emphasis added):

90. A patient interface . . . comprising:
an elbow connector . . . ;
an outer flap adapted to conform to the user's mouth and in fluid connection with said elbow connector such that said outer flap applies a compressive force around the user's mouth when worn . . . ; and
nasal cannula

For reasons similar to those discussed above with respect to Claim 68, the applied art fails to teach or suggest or otherwise render obvious at least a patient interface comprising an outer flap adapted to conform to the user's mouth such that said outer flap applies a compressive force around the user's mouth when worn.

Nowhere does Feinberg or Dietz, alone or combined, teach or suggest a patient interface comprising an outer flap *adapted to conform to the user's mouth* such that said outer flap applies a compressive force *around the user's mouth* when worn.

Goldstein fails to cure the deficiencies of the Feinberg-Dietz combination, as Goldstein merely describes an apparatus that "includes a dentally stabilized platform and a nose mask, nose piece or nasal tubes resiliently mounted on the platform and urged toward nasal engagement and rhinal seal." Goldstein, Abstract; *see also* Figure 14, reproduced below.



Therefore, for at least these reasons, Claim 90 distinguishes over the applied art.

Claims 79, 80, 82, and 83 depend from Claim 68, and therefore distinguish over the applied art for at least the same reasons discussed above with respect to Claim 68. In addition, Claims 79, 80, 82, and 83 distinguish over the applied art due to the unique combinations of features recited in those claims.

Claims 85-87

Claims 85-87 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Feinberg in view of Goldstein. Applicants respectfully traverse the rejection as the applied art fails to teach, suggest, or otherwise render obvious all of the claim language.

For example, Claim 85 recites, among other things (emphasis added):

85. A patient interface . . . comprising:
an elbow connector . . . ;
an outer flap adapted to conform to the user's mouth and in fluid connection with said elbow connector *such that said outer flap applies a compressive force around the user's mouth when worn* . . . ; and
nasal cannula . . . ;
nasal cannula extension mechanism adapted to allow said nasal cannula to adjustably extend from at least one of said elbow connector and said outer flap.

For reasons similar to those discussed above with respect to Claims 68 and 90, the applied art fails to teach or suggest or otherwise render obvious at least a patient interface comprising an outer flap adapted to conform to the user's mouth such that said outer flap applies a compressive force around the user's mouth when worn.

Nowhere does the applied art, alone or combined, teach or suggest a patient interface comprising at least an outer flap *adapted to conform to the user's mouth* such that said outer flap applies a compressive force *around the user's mouth* when worn. Therefore, for at least these reasons, Claim 85 distinguishes over the applied art.

Claims 86 and 87 depend from Claim 85, and therefore distinguish over the applied art for at least the same reasons discussed above with respect to Claim 85. In addition, Claims 86 and 87 distinguish over the applied art due to the unique combinations of features recited in those claims.

Claims 89

Claim 89 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Feinberg in view of Robertson and further in view of Daniell. Applicants respectfully traverse the rejection as the applied art fails to teach or suggest or otherwise render obvious all of the claim language, and because the Office Action improperly combines the applied art in an impermissible manner that renders it unsuitable for its intended use.

Claim 89 recites, among other things (emphasis added):

89. A patient interface . . . comprising:
an elbow connector . . . ;
an outer flap adapted to conform to the user's mouth and in fluid connection with said elbow connector, *said outer flap providing a substantial seal about the outside of the user's mouth* and capable of delivering said gases from said elbow connector to the user's oral passage; nasal cannula . . . ; and
an outlet vent in fluid communication with said elbow connector to allow diffusion of the user's exhaled gases.

Claim 89 requires an outer flap adapted to conform to a user's mouth, the outer flap providing a substantial seal about the outside of the user's mouth, and an outlet vent in fluid communication with the elbow connector to allow diffusion of the user's exhaled gases.

In contrast to the language of Claim 89, and as discussed above, Feinberg fails to teach or suggest such either an outer flap adapted to conform to the user's mouth or an outer flap providing a substantial seal about the outside of the user's mouth. In contrast, as discussed above, instead of describing any sort of sealing, Feinberg explains that his "flange 15 is spaced from the body of the member 10 so as to provide a space for the lips between it and the elongated flange 15." Therefore, the body of Feinberg's breathing apparatus need not even touch the swimmer's face, let alone provide a substantial seal about the outside of the user's mouth during use.

In addition, as discussed above with respect to Claims 71 and 72, the Office Action improperly combines Feinberg with Daniell in a manner that would render Feinberg unsuitable for its intended use. M.P.E.P. 2143.01.

Therefore, for at least these reasons, Claim 89 distinguishes over the applied art.

New Claims

New Claims 92-97 find support throughout the application as originally filed. Therefore, no new matter is introduced with these claims.

Claims 92-97 depend from Claim 68 and therefore distinguish over the applied art at least for the same reasons discussed above with respect to Claim 68. In addition, Claims 92-97 distinguish over the applied art due to the unique combinations of features recited in those claims.

For example, Claim 93 describes a patient interface further comprising an adjustment mechanism that allows the user to adjust the compressive force applied to the user's mouth when worn by adjusting a distance between the elbow connector and the outer flap. The applied art is silent to at least this language.

Claim 94 further limits Claim 93 by requiring the adjustment mechanism comprise a sliding sleeve. The applied art is silent to at least this language, as well.

Claim 95 describes a patient interface further comprising at least one outlet vent in fluid communication with an elbow connector to allow diffusion of the user's exhaled gases. For reasons similar to those discussed above with respect to Claims 71, 72, and 89, Claim 95 distinguishes over the applied art at least because the combination applied to those claims impermissibly renders the art unsuitable for its intended purpose.

Claim 96 describes a patient interface further comprising a vestibular shield configured to be inserted between the patient's lips and gums during use, wherein a distance between the outer flap and the vestibular shield is adjustable to apply sufficient compressive force around the user's lips to maintain the outer flap in contact with the patient while the patient sleeps. The applied art is silent to at least this language, as well.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution.

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Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used, unless otherwise noted. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion alone or to imply that the limitation discussed is essential or critical. Rather, patentability rests on each claim taken as a whole; it is the combination of features or acts recited in a claim that distinguishes it over the art of record.

Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Applicants may not have presented all arguments concerning how the applied references do not render the claims anticipated or obvious, or how the references cannot be properly combined or modified in view of their deficiencies. Accordingly, Applicants reserve the right to later present additional arguments of patentability—for example, to later contest whether a proper motivation and suggestion exists to combine or modify any of the applied references.

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is requested.

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The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicants' attorney, in order to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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